PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
SF0820K2		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US99/22269	23/09/1999	25/09/1998
International Patent Classification (IPC) or national classification and IPC C07K16/28		
Applicant SCHERING CORPORATION et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30/03/2000	23.11.2000
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Giry, M Telephone No. +49 89 2399 7328

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/22269

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-77 as originally filed

Claims, No.:

1-15 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:
see separate sheet

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4, 10-15
	No:	Claims	1-3, 5-9
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-15
Industrial applicability (IA)	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item I

Basis of the report

The sequence listing (p. 1-12) filed on 05.11.1999 is also included in the basis of the opinion.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 - **Reference** is made to the following document :

D1 : J. Valladeau et al.: 'DCGM4, a potentially novel protein selectively expressed by Langerhans-type human dendritic cells.' J. Invest. Dermatology, vol. 109, no. 2, August 1997, page 267

2 - **Novelty** - Art. 33(1) and (2) PCT :

The present application discloses a cell surface antigen specific for Langerhans cells, *i.e.* Langerin, a monoclonal antibody (mAb) directed to Langerin and nucleic acid sequences encoding this protein.

Document D1 reports on DCGM4, a 40-50 kD glycoprotein, on a mAb directed to DCGM4 and on its use for the determination of DCGM4 expression among various dendritic cells populations. According to the description (p. 3, lines 15-18), DCGM4 and Langerin correspond to one and the same protein. Therefore, D1 appears to be novelty destroying for claims 1-3 and 5-8.

The expression "a fragment of" renders the subject-matter of claim 9 unclear as long as the length of the fragment is not indicated. As a single amino acid could

be regarded as a "fragment" of a protein, the subject-matter of claim 9 is anticipated by every prior art document disclosing a polypeptide and cannot be considered as new.

Since the hybridoma cell line disclosed in claim 4 is not mentioned in D1, the said claim can be considered as novel.

The subject-matter of claims 10-15 can be regarded as new since the available prior art documents teach neither Langerin fragment nor Langerin nucleic acid sequences.

3 - **Inventive step** - Art. 33(1) and (3) PCT :

Claims 4 and 10-15 differ from document D1 in the identification of a given hybridoma cell line and nucleic acid sequences encoding Langerin. The problem underlying the present application can therefore be seen in providing new mAb and nucleic acid sequences. However, such a completion of the teaching available from the prior art would readily occur to the skilled person, especially as this is explicitly suggested in D1.
Therefore, no inventive step can be acknowledged for claims 4 and 10-15.

4 - **Industrial applicability** - Art. 33(1) and (4) PCT :

The subject-matter of claims 1-15 appears to be industrially applicable.

Re Item VII

Certain defects in the international application

a - The expression "incorporated herein by reference" employed *e.g.* on p. 4, lines 31-32 of the description is not allowed as the application should be self-contained (Art. 5 and Rule 9.1(iv) PCT, see also PCT Guidelines II-4.17).

b - The vague and imprecise statement "scope of the invention" *e.g.* on p. 6, lines 27-28 of the description implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity when used to interpret them. Such expressions are not allowed (Art. 6 PCT, PCT Guidelines III-4.3a).

c - The term "and/or the like" used *e.g.* on p. 51, line 2 renders the description unclear (Art. 5 PCT, see also PCT Guidelines III-4.3a).

d - The term "Lymphoprep" employed on p. 55, line 21 of the description appears to be a registered Trade Mark (PCT Guidelines II-4.16).

Re Item VIII

Certain observations on the international application

a - In claim 1, the definition of the term "polypeptide" is unclear, since according to the description, this term can be defined by its amino acid sequence (Art. 6 PCT).

b - Claim 5 as disclosed, does not enable the skilled person to determine which technical features are necessary to perform the "method for analysing a cell population". Therefore, the matter for which protection is sought is not clearly defined (Art. 6 PCT).

c - Claims 7-15 lack clarity since their subject-matter, defined by an indefinite term ("a"), concerns either "a" protein or "a" nucleic acid but having "a" precisely **determined** sequence (Art. 6 PCT).

d - Claim 6 lacks clarity since the protein is defined by its ability to bind the antibody disclosed in claim 1. However, the antibodies of claim 1 are not limited to the specific DCGM4 antibody, but encompasses unspecific antibodies as well. Thus, claim 6 is not properly defined. Moreover, only the part of the protein which has the sequence shown in SEQ ID NO: 2 is supported by the description, this being the only isolated and purified form (p. 5, line 27) (Art. 6 PCT).

e - Furthermore, the terms "substantially" and "approximately" used in claim 6 have no well-recognized meaning and leave the reader in doubt as to the meaning of the technical features to which it refer, thereby rendering the definition of the subject-matter of said claim unclear (Art. 6 PCT).